

### REMARKS

Claims 1-11 were pending in this application. According to the October 22, 2002 Office Action, claims 1-11 were finally rejected. Applicants have amended claim 1. Accordingly, claims 1-11 are under consideration. Applicants maintain that the amendments do not introduce any new matter. Specifically, support for the amendments of claim 1 may be found in the specification on page 2, line 29 to page 4, line 34 where procedures for the preparation and specific examples of microcapsules according to the present invention are described. These procedures, when practiced, inherently result in microcapsules without the pharmaceutical peptide on their surfaces.

### Rejection under 35 U.S.C. §103(a)

The Examiner rejected claims 1-11 under 35 U.S.C. §103(a) as allegedly unpatentable over Fuisz in view of Yamamoto et al., Bodmer et al. and Canal et al.

In response, Applicants respectfully traverse the Examiner's rejection. Nonetheless, Applicants have amended claim 1 to indicate that the surface of the claimed microcapsule does not contain the peptide of pharmaceutical interest.

Fuisz describes the preparation of controlled release delivery systems by melt-spun process. This process is characterized in that the product obtained is a uniform mixture of encapsulating agent (polymer) and drug. Therefore, a drug is present on the surface of the particles obtained by this method. The product according to the present patent application is obtained by a process that yields a product constituted by a **nucleus** of drug, which is coated by a layer of polymer. Thus, as indicated by the amended claim 1, the particles of the present invention do not contain a drug on their surface. Furthermore, capsules, according to the common knowledge of a person skilled in the art do always comprise at least a thin coating, which does not contain the drug. The compositions according to Fuisz et al will always contain some drug on their surface, as the drug is homogeneously distributed through the polymer. Therefore, the release of the drug from the microcapsules according to the present patent application are completely different from the product described in Fuisz.

Yamamoto et al., Bodmer et al. and Canal et al. all describe the preparation of microcapsules incorporating different drugs such as the ones disclosed by the present invention.

The Examiner alleged that a person skilled in the art would have been motivated to combine any of the encapsulated peptides of Yamamoto et al., Bodmer et al. and Canal et al. with the formulation of Fuisz to arrive at the present invention. Based on the above remarks, even if one is to combine the teachings of all the cited prior art as the Examiner indicated, one would not arrive at the present invention because the design of the formulation of Fuisz is radically different from the present formulation because it is intended for a different purpose.

Accordingly, Applicants respectfully submit that the references cited either alone or in combination do not disclose nor suggest the present invention. Thus, the Examiner is kindly requested to withdraw this rejection.

In light of the foregoing, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited. If there are any issues or amendments the Examiner wishes to discuss, the Examiner is encouraged to contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on February 24, 2003:

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Name of applicant, assignee or  
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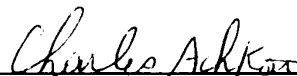


Signature

February 24, 2003

Date of Signature

Respectfully submitted,



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**APPENDIX B**  
**Version with Markings to Show Changes Made**  
**37 C.F.R. § 1.121(b)(iii) and (c)(ii)**

**CLAIMS:**

1. (AMENDED) A pharmaceutical preparation of microcapsules of lactic-co-glycolic copolymer which incorporates a peptide of pharmaceutical interest, characterised in that the copolymer that forms the microcapsules incorporates a citric acid ester as an additive and the peptide is not present on the surface of the microcapsule.